In the United States Court of Federal Claims

M.R.,

Petitioner,

v.

THE UNITED STATES,

Respondent.

No. 16-1024V
(Filed: August 2, 2023)[1]

Ronald Craig Homer, Boston, MA, for Petitioner.

Sarah Black Rifkin, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

LERNER, *Judge*.

Petitioner, M.R., seeks review of Chief Special Master Brian H. Corcoran's October 3, 2022 decision ("Decision"), ECF No. 82, denying the Petitioner compensation. Petitioner brought this action pursuant to the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-10 *et seq.*, alleging that the influenza ("flu") vaccine caused him to develop left-sided sensorineural hearing loss ("SNHL"). Chief Special Master Corcoran denied the Petition, finding that an alternative cause/factor unrelated to the vaccination caused his hearing loss. Petitioner contends that the Chief Special Master's decision was arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law. Mot. for Rev., ECF No. 89.

For the reasons explained below, Petitioner's Motion for Review is **GRANTED**. The Chief Special Master's decision is **VACATED**, and the case is **REMANDED** for further action in accordance with this opinion, to include development of the record as appropriate.

[1] Petitioner's name has been redacted to initials pursuant to Rule 18(b) and the Chief Special Master's Order Granting Motion to Redact. Rules of the United States Court of Federal Claims, App. B, Rule 18(b) ("Vaccine Rules"); ECF No. 87. Additionally, this Opinion was initially filed on March 27, 2023, and the parties were afforded fourteen days to propose redactions. The parties did not. Accordingly, this Opinion is reissued in its original form for publication.

I. Background

A. Factual Background[2]

Petitioner was forty-nine years old when he received a flu vaccine in his left arm on October 21, 2014. Pet. at 1, ECF No. 1; Pet'r's Ex. 18 at 1, ECF No. 10-1 (M.R. affidavit). He had a history of morbid obesity, urinary tract stone disease, allergic rhinitis, elevated cholesterol/triglycerides, and elevated hemoglobin A1C. Tr. at 6; Pet'r's Ex. 2 at 2–5, 8–10, 23–24, ECF No. 5-2; Pet'r's Ex. 3 at 3–4, ECF No. 5-3. Petitioner identified at least three prior vaccinations against the flu—all of which had no adverse side effects. Pet'r's Ex. 12 at 14, ECF No. 6-3.

The day after the vaccination, Petitioner reported that he "started to develop a little soreness at the injection site." *Id.* at 6–8. "[O]ver the next four days, [he] had pain that traveled from the site up across [his] shoulder to [his] neck and then traveled up to the side of [his] neck." *Id.* Four days post vaccination, Petitioner began to experience hearing loss in his left ear and sudden bouts of vertigo. Tr. at 8. On the morning of October 27, 2014, he "felt [his] hearing go . . . and the vertigo hit." *Id.* Later that day, Petitioner went to the emergency room at Robert Wood Johnson Hospital in New Jersey, "complaining of severe vertigo with hearing loss to the left ear." Pet'r's Ex. 7 at 113, ECF No. 5-7. His reports did not reference the flu vaccine. *Id.* Petitioner underwent a CT scan, which revealed no abnormalities. *Id.* at 114–15. After the CT scan, his physicians diagnosed him with acute labyrinthitis. *Id.* at 113–14. The differential diagnoses also included a cerebellopontine angle ("CPA") tumor.[3] Tr. at 114–15.

On October 30, 2014, Petitioner saw an otolaryngologist, Dr. Michael Goldrich, for his hearing loss and vertigo. Pet'r's Ex. 5 at 43, ECF No. 5-5. An audiogram later revealed profound sensorineural hearing loss ("SNHL") in Petitioner's left ear. *Id.* at 46, 54–55. The following day, Dr. Goldrich performed a left myringotomy, tube insertion, and steroid instillation. Pet'r's Ex. 7 at 1, 15, 50. Dr. Goldrich's procedure notes state that "5 days [after] flu vaccine on 10/21/14 [patient with] reports of hearing loss [in his left] ear." *Id.* at 25.

On November 3, 2014, Petitioner met with both Dr. Goldrich and an otolaryngology surgeon, Dr. Jed Kwartler. Pet'r's Ex. 9 at 16, ECF No. 5-9. In conversation with Dr. Kwartler, Petitioner denied any recent viral illness but mentioned that he "did have a flu shot prior to the onset of symptoms." *Id.* Dr. Kwartler prescribed a series of therapies and ordered an MRI. *Id.*

Before undergoing an initial hyperbaric oxygen therapy, Petitioner reported slight improvement. *Id.* (Between November 5 and December 15, 2024, Petitioner underwent twenty-three hyperbaric oxygen treatments. *Id.* at 1, 51.) The physician administering the therapy noted

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[2] The facts of this case are set forth in their entirety in the Chief Special Master's Decision.

[3] The cerebellopontine angle is "the space between the cerebellum pons and the temporal bone. [I]t's the area where the seventh and eighth nerves travel from the brainstem to get into . . . the internal auditory canal." Tr. at 114. An acoustic neuroma, *see infra* note 4, is a type of CPA tumor. Tr. at 93, 115.

that Petitioner was "scheduled to have an MRI . . . to make sure that there [wa]s no evidence of acoustic neuroma."[4] Tr. at 118.

On November 10, 2014, the MRI revealed an acoustic neuroma in the "distal aspect of the left internal auditory canal." Pet'r's Ex. 5 at 58. Dr. Kwartler cautioned that if Petitioner did not recover his hearing, "it might be reasonable to proceed with a translabyrinthine approach for tumor removal" or repeat the MRI in six months "to monitor for any growth." Pet'r's Ex. 9 at 14.

On November 20, 2014, Petitioner again reported improvement for his vertigo. Pet'r's Ex. 5 at 23. While an audiogram showed "some improvement in bone conduction levels on the left [ear]," a second audiogram on December 16, 2014, showed "no improvement in hearing on the left [ear] after 20[-plus] treatments with hyperbaric oxygen." *Id.* at 19. On April 17, 2015, Dr. Kwartler surgically placed the bone-anchored hearing aid ("BAHA") implant for Petitioner. Pet'r's Ex. 11 at 25, ECF No. 6-2. Between 2015 and 2021, Petitioner underwent six more MRIs, all of which confirmed that the size of the acoustic neuroma remained unchanged. Pet'r's Ex. 15 at 2, 4, ECF No. 6-6; Pet'r's Ex. 17 at 1, ECF No. 6-8; Pet'r's Ex. 25 at 1, ECF No. 51-1; Tr. at 15. He testified that even with the BAHA, his hearing is only at 50 percent in his left ear. Tr. at 17. He also expressed concern that his insurance would not cover the cost of a BAHA replacement (approximately $5,000), typically required within four to five years. *Id.* at 18–19.

B. Expert Testimony

1. Petitioner's Expert

Dr. Edwin Monsell described the flu vaccine's relationship to SNHL in two expert reports. *See generally* Tr. at 24–104, 151–58; Pet'r's Ex. 22, ECF Nos. 24-1, 66–69 ("Monsell First Rep."); Pet'r's Ex. 24, ECF Nos. 70–71, 77 ("Monsell Second Rep."). Dr. Monsell proposed a causal mechanism for sudden SNHL in the form of the "stress response theory." Tr. at 45. Dr. Monsell cited medical literature which hypothesizes that sudden SNHL most likely results from activation of cell stress pathways involving the nuclear factor kappa beta ("NF-kB"). Pet'r's Ex. 24, Tab G ("Merchant"), ECF No. 70-8; Tr. at 45–46. NF-kB is the master immune complex that regulates inflammation and responds to injury in the tissue. Tr. at 46; Monsell First Rep. at 5; *but see* Merchant at 158 (noting that none of the studied patients had acoustic neuromas). One study speculated that sudden SNHL might reflect the end-result of rapid progression of events after NF-kB activation. Tr. at 47; Monsell Second Rep. at 1; Merchant at 158–59.

[4] "An acoustic neuroma, or vestibular schwannoma, is 'a progressively enlarging, benign tumor, usually within the internal auditory canal . . . . [T]he symptoms, which vary with the size and location of the tumor, may include hearing loss, headache, disturbances of balance and gait, facial numbness or pain, and tinnitus.'" Decision at 3 n.6 (quoting *Acoustic Neuroma*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=92588 (last visited Oct. 3, 2022)).

Dr. Monsell cited additional literature expounding upon the link between NF-kB and SNHL. Tr. at 49–50, 81–82; Monsell Second Rep. at 1; Pet'r's Ex. 24, Tab B, ECF No. 70-3 ("Adams"); Pet'r's Ex. 24, Tab C, ECF No. 77-1 ("Adams & Seed"). Those studies proposed that SNHL associated with NF-kB could be explained by the disruption of the normal balance of inflammatory cytokines. Adams at 321; Tr. at 49–50; Monsell Second Rep. at 1. Theoretically, when the body experiences a systemic immune challenge, this "can stimulate the immune system in the inner ear, in the cochlea right where all these sensitive structures are." Tr. at 49. However, given the "sparse experimental evidence," the theory remains speculative. Adams at 321.

Dr. Monsell then postulated how the flu vaccine could cause SNHL through the stress response theory. Tr. at 51–53; Monsell Second Rep. at 1; *see generally* Adams & Seed at 536–38 (describing how this mechanism works in an animal model). He proposed that administration of the vaccine would increase circulating cytokines. Tr. at 52. According to Dr. Monsell, the literature shows that the flu vaccine can result in both a mild, measurable, acute phase reaction and an immediate increase in a cytokine known to stimulate NF-kB. *See, e.g.*, *id.* at 52, 102–04; Monsell First Rep. at 5; Pet'r's Ex. 30 at 2739–41, ECF No. 53-2 ("Carty"); Pet'r's Ex. 22, Tab Q, ECF No. 67-7 ("Liuba") (demonstrating inflammation following the administration of the flu vaccine in humans but noting that the relatively low number of individuals in the study and short duration of follow-up preclude definitive conclusions regarding the significance of their findings). The medical literature also demonstrated the possibility of NF-kB stimulation in the ear. Tr. at 79–80. The Special Master found that the article did not discuss hearing loss whatsoever. Decision at 12.

Despite Petitioner's recent history of receiving the flu vaccine without adverse effects, Dr. Monsell alleged that the stress response theory was still applicable. Tr. at 87. He believed it was possible that Petitioner was exposed to antigens throughout the vaccinations but that he only reacted to the antigens after the most recent dose. *Id.* He also claims Petitioner's age and environmental factors should be taken into account. *Id.* at 87, 101; *see also* Pet'r's Ex. 12 at 15. However, Dr. Monsell acknowledged that aside from a local reaction, the record revealed no evidence of any objective markers of inflammation around the time of hearing loss onset. Tr. at 101; Monsell Second Rep. at 1.

Dr. Monsell opined that Petitioner's acoustic neuroma was unlikely the cause of his SNHL. He believed Petitioner's SNHL significantly differed from other cases of acoustic neuroma present with sudden SNHL. Tr. at 64, 69–71, 93–94; Monsell Second Rep. at 2–3. Dr. Monsell also alleged that the tumor was too small to cause severe hearing loss. Tr. at 64, 69–71, 100. Respondent's expert disagreed, and in fact suggested that the opposite is true, stating "it's been reported that sudden sensorineural hearing loss is more frequently encountered in small tumors less than 1 centimeter than in medium-sized tumors greater than 1 centimeter." Tr. at 123. Dr. Monsell responded that it is not helpful to rely on studies examining the correlation between tumor size and level of hearing loss because "those correlational studies are done with putting tumors into categories, small, medium, large, very large . . . [a]nd this tumor is smaller than small." *Id.* at 94–95. Thus, tumors the size of Petitioner's were not categorized in these studies. *Id.* However, Dr. Monsell could not identify any of these studies. Tr. at 95.

Dr. Monsell believed that Petitioner's medical history supported the conclusion that the flu vaccine most likely caused his sudden SNHL. Tr. at 60, 70–72; Monsell First Rep. at 6. Prior to vaccination, Petitioner's hearing and balance were normal. Tr. at 60–61. Even if Petitioner already possessed an acoustic neuroma pre-vaccination, Dr. Monsell could not find evidence of any alternative cause for Petitioner's SNHL other than vaccination. Tr. at 61, 71. Dr. Monsell also alleged that the medical record consistently referenced Petitioner's vaccination in relation to his hearing loss. Tr. at 61.

According to Dr. Monsell's testimony, the onset of Petitioner's symptoms (four days after vaccination) was a medically appropriate timeframe in which the proposed inflammatory mechanism would occur. Tr. at 71. Dr. Monsell suggested hearing loss symptoms could occur anywhere between one day and a few weeks after, but typically take a few days to manifest. *Id.* at 71–72.

Ultimately, the Chief Special Master found that Dr. Monsell's opinion was deficient as to the causal connection between the flu vaccine and SNHL. Much of the literature Dr. Monsell relied upon involved vaccines for different illnesses and other forms of the flu vaccine, rather than the inactivated flu vaccine that Petitioner received. Decision at 13, Tr. at 73–76; Monsell First Rep. at 2–3; Pet'r's Ex. 22, Tab A, ECF No. 66-1 ("Asatryan"). Dr. Monsell could not identify any study specifically addressing the situation of patients like Petitioner with acoustic neuromas who also received the flu vaccine. Tr. at 98.

2. Respondent's Expert

Dr. Bigelow prepared two expert reports to dispute the flu vaccine's alleged role in causing hearing loss. *See generally* Tr. at 106–51; Resp't's Ex. A, ECF No. 29-1 ("Bigelow First Rep."); Resp't's Ex. C, ECF No. 34-1 ("Bigelow Second Rep."). Based on his review of the literature, he did not believe that the flu vaccine can cause or is associated with SNHL. *Id.* at 126; Bigelow First Rep. at 9; Bigelow Second Rep. at 6 (citing Resp't's Ex. C at 85, ECF No. 34-7 ("Baxter") (study of over eight million vaccine doses finding no correlation between vaccination and sudden hearing loss)). He also opined that the manifestation of Petitioner's vertigo and hearing loss four days after vaccination was not probative of causation. Tr. at 125, 136, 147–48; Bigelow First Rep. at 9, 10 (citing Baxter at 84) (concluding that a heightened risk of association existed in a longer timeframe than four days).

Additionally, Dr. Bigelow argued that Dr. Monsell's literature review addressed different vaccines entirely and thus was not applicable to the instant case. Tr. at 126–27; Bigelow First Rep. at 9–10; Asatryan at 1166, 1168. For instance, Dr. Monsell relied on studies concerning the measles and mumps vaccine. Tr. at 126–27; Bigelow First Rep. at 9–10; Asatryan at 1166, 1168. Dr. Bigelow explained that measles and mumps are known to cause profound SNHL, so patients may develop SNHL after receiving a live vaccine. Tr. at 127. But Dr. Bigelow stated that the research on the measles and mumps vaccine is not transferrable to the instant case. *Id.* Petitioner was given an inactive version of the flu vaccine, while the measles and mumps vaccine contains live viral remnants. *Id.* He concluded that any evidence that the live flu virus can cause SNHL is inapposite. *Id.*

Respondent's expert also countered Dr. Monsell's stress response theory of causation. Tr. at 127–29, 138; Bigelow First Rep. at 10. He admitted that he had not submitted literature disputing the validity of this theory, but believed there would be more cases of sudden hearing loss if it were scientifically valid. Tr. at 144. He questioned Dr. Monsell's reliance on a study regarding the activation of NF-kB cells because it did not involve human subjects. Tr. at 128, 138–39, 141–43; Bigelow Second Rep. at 6; Merchant at 158–59. Even if Dr. Monsell's stress response theory were correct, Dr. Bigelow stated he would have expected the steroid treatments to reduce inflammation enough to mitigate any sudden hearing loss. Tr. at 129 (citing Adams & Seed at 537). But Dr. Bigelow noted that steroid treatments were ineffective for Petitioner, further undermining the applicability of Dr. Monsell's stress response theory. *Id.*

His testimony also noted that none of Petitioner's treating physicians proposed an association of Petitioner's SNHL with the flu vaccine. *Id.* at 129. Instead, they merely included the vaccination in their notes as an event reported by Petitioner. *Id.* Dr. Bigelow noted that Petitioner's other post-vaccination symptoms—including inflammation at the injection site and pain radiating up to his neck and left ear—are common and are likely unrelated to sudden hearing loss. *Id.*

Ultimately, Dr. Bigelow proposed that the most likely cause of Petitioner's SNHL was his acoustic neuroma. Tr. at 130–31, 132, 145–46; Bigelow First Rep. at 8–11; Bigelow Second Rep. at 5 (explaining that the risk of SNHL in patients with acoustic neuromas is "many times higher than in the general population"). He also stressed that acoustic neuromas can cause profound hearing loss regardless of the tumor size. Tr. at 124, 132. He believed that Petitioner's acoustic neuroma likely existed prior to his vaccination but was asymptomatic. *Id.* at 135–36.

II. Jurisdiction and Standard of Review

This Court possesses jurisdiction, pursuant to the Vaccine Act, to "remand the petition to the special master for further action in accordance with the court's direction." 42 U.S.C. § 300aa-12(e)(2)(C). It can also "reverse the decision of a special master when the special master has failed to adequately develop the record, failed to consider facts critical to the case, failed to give adequate consideration to a viable medical theory, or otherwise misapplied the law." *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009).

III. Discussion

A. Legal Standards

A petitioner may establish that a vaccine caused an alleged injury in one of two ways. First, a petitioner benefits from a "statutorily-prescribed presumption of causation" if their injuries and vaccination records align with the Vaccine Injury Table at 42 U.S.C. § 300aa-14(a). *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (describing a "[t]able injury"). SNHL is not a table injury for the flu vaccine. 42 U.S.C. § 300aa-14(a). If an injury is off-table, a petitioner must "prove by a preponderance of the evidence" that a particular vaccine caused the alleged injury. *Althen*, 418 F.3d at 1278.

In *Althen*, the United States Court of Appeals for the Federal Circuit comprehensively described the petitioner's burden and developed a three-prong test for establishing a prima facie case under the Vaccine Act:

> To meet the preponderance standard, [petitioner] must "show a medical theory causally connecting the vaccination and the injury." *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted). A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]" *Grant*, 956 F.2d at 1148. [Petitioner] may recover if she shows "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface* [*v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)]. Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation. *See Grant,* 956 F.2d at 1149. Concisely stated, [petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. If [petitioner] satisfies this burden, [they are] "entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 547 (Fed. Cir. 1994) (alteration in original) (citation omitted).

418 F.3d at 1278; *see also Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1324 (Fed. Cir. 2006).

Importantly, "the petitioner need not show that the vaccine was the sole or predominant cause of [their] injury, just that it was a substantial factor." *De Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008) (quoting *Walther v. Sec'y of Health & Hum. Servs.*, 485 F.3d 1146, 1150 (Fed. Cir. 2007); *Shyface*, 165 F.3d at 1352. The Federal Circuit has recognized that "concurrent forces may bring about a single harm." *Shyface*, 165 F.3d at 1352. Such cases require "weighing the contributing factors." *Id.* Additionally, "close calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

The Vaccine Act establishes a burden-shifting framework. *E.g.*, 42 U.S.C. § 300aa-13(a)(1); *de Bazan*, 539 F.3d at 1353–54; *Pafford*, 451 F.3d at 1355; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). If the petitioner establishes a prima facie case, the burden shifts to the respondent to prove, by a preponderance of the evidence, that "factors unrelated" to the vaccination were "principally responsible" for causing the injury. 42

U.S.C. § 300aa-13(a); *de Bazan*, 539 F.3d at 1353–54; *Pafford*, 451 F.3d at 1355. Like the petitioner, the respondent must demonstrate that the "factor unrelated" was the actual cause of the injury, i.e., that it was both a but-for cause and a substantial factor in bringing about the injury. *See Knudsen*, 35 F.3d at 547 ("[I]f a petitioner has proved actual causation or obtained the benefit of a presumption, and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation."); *Shyface*, 165 F.3d at 1352 (establishing that actual causation requires showing the alleged cause was both a but-for cause and a substantial factor).

The special master cannot "require the petitioner to eliminate alternative causes as part of establishing its prima facie case." *Doe 11 v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1357–58 (Fed. Cir. 2010). However, "when petitioners attempt to eliminate other possible causes to buttress their theory of causation, the special master should evaluate such evidence in determining whether a prima facie case has been established." *Id.* at 1358. Indeed, the Government is permitted to offer, and the special master is permitted to consider, evidence of alternative causes in evaluating the record as a whole when deciding whether the petitioner has established a prima facie case. *Id.* ("Like any defendant [the government] is permitted to offer evidence to demonstrate the inadequacy of petitioner's evidence on a requisite element of the petitioner's case-in-chief.") (quotation marks omitted) (quoting *de Bazan*, 539 F.3d at 1353); *Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("Our decisions support the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."). In so doing, the respondent is not held to any burden of proof to establish the alternative cause. *See Doe 11*, 601 F.3d at 1358.

The Federal Circuit has distinguished between cases where only one of multiple potential "forces . . . independently caused a harm" and those where multiple potential "forces . . . combine[d] to produce a harm":

> [I]n cases involving multiple independent potential causes, if it is clear 'that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it' . . . the government has the burden to prove that the covered vaccine did not cause the harm.

Walther, 485 F.3d at 1151 (quoting Restatement (Second) of Torts § 433B(3)). On the other hand:

> When a case involves multiple causes acting in concert, [the Federal Circuit] recognized in *Shyface* that a petitioner need not show the asserted vaccine was the predominant cause, but must show that it was substantial. Where multiple causes act in concert to cause the injury, proof that the particular vaccine was a substantial

> cause may require the petitioner to establish that the other causes did not overwhelm the causative effect of the vaccine.

Id. at 1151 n.4 (citations omitted). This is consistent with the rule prohibiting the special master from requiring the petitioner to rule out other potential causes. *See id.* at 1151; *Doe 11*, 601 F.3d at 1357–58.

B. Analysis

The Chief Special Master denied the Petitioner's claim, finding that R.'s acoustic neuroma was more likely to have caused his SNHL than the flu vaccine. Decision at 29–31. Petitioner's primary challenge to the Chief Special Master's Decision is that he misapplied *Shyface* in stating: "I would not find in this case, under a '*Shyface*' analysis, that the flu vaccine and the neuroma were equally potentially causative, permitting an entitlement decision for Petitioner." Decision at 30 n.38 (citing 165 F.3d at 1352–53).[5]

This Court finds that the Chief Special Master's Decision and record lack the clarity necessary for a thorough review of the Decision's legal and factual bases. Accordingly, pursuant to 42 U.S.C. § 300aa-12(e)(2)(C), this case is remanded to the Chief Special Master for further proceedings to clarify his findings, perform a thorough causation analysis in accordance with the applicable standards, and develop the record as may be needed for that analysis.

Specifically, it is not apparent from the Chief Special Master's findings of fact whether he found that: (1) there was no evidence supporting the vaccine as a cause; or (2) evidence supported the vaccine as a cause, but that the acoustic neuroma either (a) "overwhelmed" the vaccine as a contributing factor; or (b) was the independent cause of Petitioner's injury. *See, e.g.*, *Walther*, 485 F.3d at 1151 n.4. Such findings are necessary to determine the correct analytical framework for causation and burdens of proof. *See, e.g.*, *id.* In his brief analysis, the Chief Special Master found that the evidence in this case "preponderantly supports the conclusion that it was the neuroma (which likely predated vaccination) that produced Petitioner's SNHL and not the vaccine." Decision at 31. He did so without first determining that Petitioner established a prima facie case because "the alternative cause evidence is strong enough to be dispositive of the claim overall . . . since it precludes the determination that the vaccine 'did cause' his SNHL (*Althen* prong two)." *Id.* at 29–30.

As discussed above, a special master may consider evidence of an alternative cause in weighing a petitioner's case in chief without requiring the respondent to prove, by a

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[5] Petitioner also argues that the Chief Special Master erred in finding that various notes from treating physicians in Petitioner's medical records that he received the flu vaccine shortly before the onset of symptoms "seem[] more commonly to reflect an effort to record Petitioner's history than to evince reasoned opining as to cause." Decision at 30–31. Upon reviewing the record, this Court finds that the Chief Special Master's factual finding was reasonable as the relevant quotes from treating physicians do not suggest causation.

preponderance of the evidence, that it actually caused the injury. *E.g.*, *Stone*, 676 F.3d at 1380. However, given the two potential causes in the present case, the Chief Special Master should have followed that order of events if he finds that both potential causes acted in concert to cause a single harm. *See, e.g.*, *Walther*, 485 F.3d at 1151 n.4; *Stone*, 676 F.3d at 1380 ("[T]he special master is entitled to consider the record as a whole in determining causation, especially in a case involving multiple potential causes acting in concert."); *Pafford*, 451 F.3d at 1358–59 ("[T]he presence of multiple potential causative agents makes it difficult to attribute 'but-for' causation to the vaccination. . . . [T]he Special Master properly introduced the presence of the other unrelated contemporaneous events as just as likely to have been the triggering event as the vaccinations.").

The Chief Special Master's findings do not directly address whether he concluded that the vaccine and acoustic neuroma worked in concert. But several statements throughout the Decision could be interpreted as such. For example, even after declining to rule on whether Petitioner established a prima facie case, the Chief Special Master elaborated in a footnote on *Althen* prongs one and three, stating that "Petitioner did offer a theory with many reliable components . . . [and t]his theory was deemed sound and reliable in *Madigan* [*v. Sec'y of Health & Hum. Servs.*, No. 14-1187V, 2021 WL 3046614, at *1, *4 (Fed. Cl. Spec. Mstr. June 25, 2021) (finding flu vaccine caused petitioner's SNHL)]." Decision at 29–30 n.37. He also wrote that "Petitioner's four-day, post-vaccination onset . . . [is] consistent with the timeframe deemed medically acceptable in the few other favorable decisions involving hearing loss." *Id.*; *see Hopkins v. Sec'y of Health & Hum. Servs.*, 84 Fed. Cl. 517, 523 (2008) ("Evidence used to satisfy one of the *Althen* prongs may overlap with and be used to satisfy another prong."). The Chief Special Master also stated that "[i]t could be inferred from Petitioner's obtaining of a future flu vaccine exemption . . . that some treaters concurred as to the vaccine's likely causal role." Decision at 31 n.39; *see Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1376 (2009) ("A treating doctor's recommendation to withhold a certain vaccination can provide probative evidence of a causal link between the vaccination and an injury a claimant has sustained."). The Chief Special Master then made a factual finding that the acoustic neuroma likely predated the vaccination. Decision at 1–2, 31.

These statements suggest that the Chief Special Master believed it is possible that the vaccine and the acoustic neuroma worked in concert to cause the SNHL. The record also indicates that R.'s history of morbid obesity may have been an additional factor. Tr. at 71, 84–85 (Dr. Monsell describing severe obesity and hypertension as risk factors in developing SNHL). The Chief Special Master should have performed a *Shyface* analysis of whether each potential cause was a but-for cause and a substantial factor of the harm, and then carefully weighed the contributing factors. 165 F.3d at 1352. The Chief Special Master performed no such analysis. He held only that the vaccine and acoustic neuroma were not "equally potentially causative, permitting an entitlement decision for Petitioner." Decision at 30 n.38. This misstates the law. *Shyface* requires that the vaccine be a but-for cause and substantial factor, not the "equal," sole, or predominant cause of the injury. 165 F.3d at 1352; *de Bazan*, 539 F.3d at 1351.

The Chief Special Master relied on the "preponderance of the evidence" standard that governs the Government's attempt to prove a "factor unrelated" to the vaccine. *See* Decision at 29. This standard applies in cases that trigger the burden-shifting framework, such as where only one of multiple potential causes was the independent cause of the injury. *See, e.g.*, *Walther*, 485 F.3d at 1151. However, given conflicting statements in the Decision, the Chief Special Master did not indicate whether he viewed the acoustic neuroma as the independent cause of R.'s SNHL. Thus, it is unclear why the Chief Special Master, in addition to finding that Petitioner failed to establish a prima facie case, ruled that the evidence "preponderates far more strongly in favor of the neuroma as causal." Decision at 30 n.38.

Regardless of the level of persuasion or burden of proof the Chief Special Master applied to Respondent's evidence of an alternative cause, the law still required the Chief Special Master to analyze whether the acoustic neuroma was the but-for cause and a substantial factor of the injury. *See Knudsen*, 35 F.3d at 547 ("[I]f a petitioner has proved actual causation or obtained the benefit of a presumption, and the government cannot prove actual alternative causation for whatever reason, then the petitioner is entitled to compensation."); *Shyface*, 165 F.3d at 1352 (establishing that actual causation requires showing the alleged cause was both a but-for cause and a substantial factor). However, the Decision lacks any but-for cause/substantial factor analysis.

As Petitioner points out, "a proper *Shyface* analysis *may* result in a different outcome." Mot. for Rev. at 13 n.15 (emphasis added). This holds true despite the fact that the Chief Special Master found by preponderant evidence—a higher standard than required for analyzing alternative cause evidence as part of the case in chief—that the acoustic neuroma was the most likely cause of R.'s SNHL. *See Stone*, 676 F.3d at 1380 ("[T]he special master found that the government had satisfied its 'preponderance' burden under the 'factors unrelated' defense. It is therefore unnecessary for us to address whether the special master was correct in holding . . . that the petitioner failed to make out a prima facie case of causation.").

A more careful analysis of whether the vaccine and/or the neuroma was a but-for cause and substantial factor in bringing about the injury may require further development of the record if the Chief Special Master finds the present record inadequate for the requisite analysis. Reopening the record for further factual development, or at least performing a thorough *Shyface* analysis under the existing record, could lead the Chief Special Master to weigh the strengths and weaknesses of each party's alleged cause differently. Additionally, if the Chief Special Master concludes the vaccine and acoustic neuroma potentially worked in concert, he should further develop the record to address how such a relationship might have played out in order to properly weigh the contributing factors. As it stands, the only consideration the Chief Special Master gave to this issue is his note that "Dr. Monsell offered nothing that would illuminate how causation might come about in the context of both vaccination and the presence of an acoustic neuroma." Decision at 30 n.38 (citing Tr. at 98).

Regardless of whether the Chief Special Master finds a need to reopen the record, completing a proper *Shyface* analysis could still impact the result. For example, further analysis could reveal that the evidence of the acoustic neuroma as causal is not sufficient to overwhelm the role of the vaccine (if the Chief Special Master finds that multiple potential causes acted in concert) or to conclude that the acoustic neuroma was the independent cause of Petitioner's SNHL. *See Walther*, 485 F.3d at 1151 n.4. It is of some significance to this Court that the Government's expert admitted that science has yet to explain "the mechanism by which a subclinical acoustic neuroma becomes symptomatic with hearing loss." Tr. at 135, 145. The law requires finding for Petitioner where causation comes down to a "close call." *Althen*, 418 F.3d at 1280.

IV. Conclusion

In sum, the Chief Special Master skipped necessary steps in his analysis. The resulting Decision does not sufficiently articulate the legal or factual bases for denying Petitioner compensation. Due to the Decision's lack of clarity, this Court is not in a position to make its own factual or legal findings or determine whether the Chief Special Master's overall decision to deny entitlement was arbitrary, capricious, or otherwise not in accordance with law. *See* 42 U.S.C. § 300aa-12(e)(2)(B). Instead, pursuant to its authority under 42 U.S.C. § 300aa-12(e)(2)(C), this Court remands this case to the Chief Special Master to clarify his factual findings, use the analytical framework for causation appropriate given those findings, and further develop the record as needed to perform a proper *Shyface* analysis. *See Snyder*, 88 Fed. Cl. at 718.

For these reasons, Petitioner's Motion for Review is **GRANTED**. The Chief Special Master's decision is **VACATED**, and the case is **REMANDED** for further action in accordance with this opinion, to include reopening the record as appropriate. Additionally, Petitioner's Motion to Strike (ECF No. 91) his second motion for review, which was filed inadvertently (ECF No. 90), is **GRANTED**.

IT IS SO ORDERED.

s/ Carolyn N. Lerner
CAROLYN N. LERNER
Judge